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10/535,545	05/18/2005	Eric Ferrandis	427.096	7587

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HEDMAN & COSTIGAN P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	PAPER NUMBER
1643	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,545	FERRANDIS, ERIC	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-11 and 18-22* is/are pending in the application.

4a) Of the above claim(s) *6,11,18 and 20-22* is/are withdrawn from consideration.

5)☒ Claim(s) *4,5,8 and 9* is/are allowed.

6)☒ Claim(s) *1, 10 and 19* is/are rejected.

7)☒ Claim(s) *2 and 3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-6, 8-11 and 18-22 are all the pending claims for this application.

2. Claim 7 was cancelled and Claims 1, 4, 5 and 10 were amended in the Response of 5/22/08.

3. Claims 6, 11, 18 and 20-22 are withdrawn from examination.

4. Claims 1-5, 8-10 and 19 are all the pending claims under examination.

5. Applicants amendments to the claims have necessitated new grounds for objection. This action is FINAL.

Withdrawal of Objections

Specification

6. The objection to the specification for failing to cross-reference the priority documents for the instant application is withdrawn in view of the amendment to the specification on p. 2 of the Response of 5/22/08.

Claim Objections

7. The objection to Claim 10 for the apparent typographical error at line 9, "o host cell transformed or transfected" is withdrawn. The claim has been amended to recite "a host cell transformed or transfected".

Withdrawal of Rejections

Claim Rejections - 35 USC § 101

8. The rejection of Claims 4 and 5 under 35 U.S.C. 101 for reading on the polynucleotide per se which is found in nature is withdrawn in view of the amendment of the claims to recite "isolated polynucleotide."

Objections Maintained

Specification

9. The objection to the improper use of trademarks (e.g., Superscript®) in this application has not been addressed in the Response of 5/22/08. A trademark should be capitalized wherever it appears and be accompanied by the generic terminology.

Applicants are requested to carefully check the entire specification for any other improperly identified trademarks.

Claim Objections

10. The objections to Claim 10 for the following apparent typographical errors are maintained:

a) at line 6, "immunoligical and/or" should recite "immunological and/or". The term "immunological" is still misspelled.

b) at lines 14-15, "protein human GHRN protein" is unclear because in the preamble, the recitation is for "a protein binding human GHRH."

Rejections Maintained

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. The rejection of Claims 1 and 19 for the recitation "or one of its fragments" in Claim 1 is maintained.

It is not clear if the fragment is referring to a fragment of the isolated polynucleotide *or* a fragment of the sequence SEQ ID NO:8.

12. The rejection of Claim 10, lines 5 and 13 for the recitation "or one of the fragments of the latter" is maintained.

It is not clear if the phrase is referring to the sequence of SEQ ID NO: 9 or SEQ ID NO:13 or both.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

13. The rejection of Claims 1, 10 and 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The claims are drawn to polynucleotide fragments of a polynucleotide comprising SEQ ID NO: 8 (Claim 1) or SEQ ID NO: 9 or SEQ ID NO:13 (Claim 10) or a

pharmaceutical composition comprising polynucleotide fragments of a polynucleotide comprising SEQ ID NO: 8 of Claim 1 (Claim 19), where the encoded protein of Claim 10 is required to have "at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation" and the encoded protein of Claims 1 and 19 are presumably also required to have a therapeutic effect for treating a proliferative disease.

Applicants allege on p. 8 of the Response in ¶2 "the specification is of sufficient scope to support the scope of "fragments" since the specification and the parent application Serial No. 10/470,112 which has been allowed to define the fragments adequately. The allowed application claims a protein (named "heterocarpin") having anti-cancer activity" and in ¶3 "the sequence of SEQ ID NO: 8 and its fragment, SEQ ID NO: 9 encode heterocarpine."

Response to Arguments

Under the Written Description Guidelines (66 FR 1099 (Jan. 5, 2001); 1242 O.G. 168 (Jan. 30, 2001)), the claimed invention must meet the following criteria as set forth.

a) Actual reduction to practice: The specification discloses the cloning and isolation of the gene for heterocarpine which is a plant-derived ligand from Pilocarpus heterophyllus which binds to human growth hormone releasing hormone (GHRH). The specification discloses the following sequences corresponding to heterocarpine:

SEQ ID NO:8- cDNA for heterocarpine (p. 28);

SEQ ID NO:9- open reading frame of cDNA for heterocarpine (p. 30); and

SEQ ID NO:13- SEQ ID NO:9 having artificially undergone deletion of the initiation codon ATG and the stop codon (p. 34);

The sequences SEQ ID NOS: 4/5 and SEQ ID NO:11/12 are disclosed as being primers used in PCR reactions for heterocarpine cloning (p. 10, lines 14-16).

The specification makes a general disclosure for isolated fragments of a "polynucleotide being such that it encodes a polypeptide having at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation" [0006]. The specification does not provide sufficient written description as to the structural features of the claimed genus of polynucleotide fragments for the polynucleotides comprising SEQ ID NOS: 8, 9 or 13 (or encoded polypeptides) and the correlation between the chemical structure and function of the genus of polynucleotide fragments, such as structural domains or motifs that "encode a polypeptide having at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation."

b) Disclosure of drawings or structural chemical formulas: the specification and drawings do not show that applicant was in possession of the polynucleotide fragments encoding a protein having at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation.

c) Sufficient relevant identifying characteristics: the specification does not identify 1) a complete structure, ii) partial structure, iii) physical and/or chemical properties, or

iv) functional characteristics coupled with correlation between structure and function for the genus of polynucleotide fragments encoding a protein having at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation.

d) Method of making the claimed invention: the specification teaches cloning the plant-derived heterocarpine DNA.

e) Level of skill and knowledge in the art: the cloning of DNAs and domain "bashing" (i.e., generating deletion mutants for a parent protein) for identifying functional regions within proteins was well established at the time of the invention.

f) Predictability in the Art: the art does not appear to teach where within the heterocarpine sequence the region encoding "at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation" would be found.

Applicants have not demonstrated with sufficient evidence the genus of polynucleotide fragments encoding proteins having "at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation". The ordinary artisan could reasonably conclude that Applicants were not in possession of the claimed genus of polypeptides at the time of application filing.

Applicants also refer to application Serial No. 10/470,112 as the "parent" application for this case. Applicants have not claimed 10/470,112 in the chain of priority for the instant filed application. The instant application is a 371 of PCT/FR02/00691

(filed 2/26/02). The claimed protein fragments in the issued patent for 10/470,112 are not the same as the polynucleotides of the instant claims and that are required to encode proteins possessing the instant claimed biological activities.

The rejection is maintained.

Enablement (1)

14. The rejection of Claims 1, 10 and 19 under 35 U.S.C. 112, first paragraph, because the specification, in lacking enablement for just any polynucleotide fragment of a polynucleotide comprising SEQ ID NO: 8, 9 or 13 or the protein encoded by the nucleotide fragment and having "at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation" is maintained.

The rejection of the claims was set forth in the Office Action of 12/18/07 as follows:

"**Disclosure in the Specification**

The interpretation of the specification with respect to the polynucleotide fragments for polynucleotides comprising SEQ ID NOS: 8, 9 or 13 is discussed supra. The specification does not provide any working examples of: 1) polynucleotide fragments encoding heterocarpin proteins having any biological activity, or 2) the functional domains for any heterocarpin proteins and polypeptides that are required to be encoded by a corresponding polynucleotide fragment. Thus the specification is strongly dispositive to one of ordinary skill in the art being enabled for making or using any polynucleotide fragments of polynucleotides comprising SEQ ID NOS: 8, 9 or 13.

The claims are not commensurate in scope with the enablement provided in the specification. The specification does not support the broad scope of the claims which encompass any size polynucleotide fragment because the specification does not disclose the following:

The specific positions and regions of the sequence(s) which can be predictably modified and which regions are critical for encoding a functional heterocarpin protein; and

The specification provides insufficient guidance as to which of the essentially infinite possible fragments is likely to be successful.

Thus, Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed polynucleotide fragments in a manner reasonably correlated with the scope of the claims broadly including any number of polynucleotide fragments. The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 19 24 (CCPA 1970).

Without such guidance, the changes which can be made in the polynucleotide structure and still encode for a functional biological activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F,2d 1200, 18 USPQ 1016 (Fed. Cir. 1991) at 18 USPQ 1026 1027 and Ex parte Forman, 230 USPQ 546 (BPAI 1986).

For example, the removal of the amino terminal histidine of glucagon substantially decreases the ability of the molecule to bind to its receptor and activate adenylate cyclase (Lin et al Biochemistry USA Vol 14:1559-1563 (1975). Thus one of skill in the art could not predict which of the N- or C-terminal nucleic acids could be deleted from any one of polynucleotide comprising a sequence of SEQ ID NO : 8, 9 or 13 in order to create a fragment based on the lack of disclosure in the specification as to which domains were critical for encoding a functional heterocaptin protein.

In view of the lack of predictability of the art to which the invention pertains, the lack of disclosure for the functional domains of the heterocarptin protein of SEQ ID NO: 8, 9 or 13 and working examples of polynucleotide fragments for any one of the polynucleotides comprising the sequence of SEQ ID NO: 8, 9 or 13, one skilled in the art would be required to perform undue experimentation."

Applicants' allegations on p. 8 in ¶3 of the Response have been considered but are not found persuasive. Applicants' allege the polynucleotide of SEQ ID NO:8 and its fragment of sequence ID NO:9 encode the heterocarpine.

Response to Arguments

The SEQ ID NO:8 is the cDNA for heterocarpine (p. 28); and the SEQ ID NO:9 is the open reading frame of cDNA for heterocarpine (p. 30). Applicants have not addressed element 2) raised in the Office Action above. Applicants' specification as filed does not define the functional domains for any heterocarpin proteins and polypeptides that are required to be encoded by a corresponding polynucleotide fragment and having "at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation." Applicants have not supplemented the record with evidence demonstrating a structure/function motif or correlation for a polynucleotide fragment encoding a protein having "at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation." The "fragment" that Applicants refer to as SEQ ID NO:9 is the polynucleotide encoding the open reading frame for the full length heterocarpine protein. Applicants have not provided any art recognizing what the minimal essential structure is in the entire protein that confers the

immunological or biological activity for the protein much less which portion of protein containing this structure would need to be encoded by a polynucleotide or any one of its fragments.

The ordinary artisan would be required to practice undue experimentation in having to determine the structure/function correlation for the heterocarpine protein much less in order to identify just any polynucleotide fragment encoding a protein having "at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation."

Enablement (2)

15. The rejection of Claim 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained.

The rejection was set forth in the Office Action of 12/18/07 as follows:

> **"Nature of the Invention/ Skill in the Art**
> Claim 19 is interpreted as being drawn to a pharmaceutical composition for treating any proliferative disease comprising an effective amount of a polynucleotide of comprising SEQ ID NO:8 or a fragment thereof and an inert carrier. The claim is examined for its intended use, i.e., treating a proliferative disease.
> The relative skill in the art required to practice the invention is a medical physician/veterinarian treating proliferative disorders with recombinant DNA technology.
> **Disclosure in the Specification**
> The specification contemplates treating proliferative disorders such as cancer with the polynucleotide of SEQ ID NO:8 or fragments thereof (p. 5, lines 20-21 and p. 6, lines 25-30), but does not disclose a single working example of the polynucleotide or fragment thereof alone much less any one of the foregoing subcloned into an expression vector, where in either form, the DNA molecule was administered to a cell culture model for proliferative disorder(s) or an animal model replicating a proliferative disorder. The specification does not disclose that the polynucleotide embodiments encompassed by the claim would produce a therapeutic effect with treatment of any proliferative disorder as a therapeutic endpoint. One skilled in the art at the time of filing would not have been enabled to practice using the pharmaceutical composition to treat any proliferative disease because of the limited disclosure in the specification.
> **Prior Art Status: DNA gene-based therapy**
> The state of the art for cancer gene therapy as discussed by Vile et al (Gene Therapy, Vol. 7, pp. 2-8, 2000) is unpredictable. Vile teaches:
>
> > The problems which gene therapy for cancer will take into the next millennium focus far less on the choice of therapeutic gene(s) to be used than on the means of delivering them. There is already a battery of genes that we know are very effective in killing cells, if they can be expressed at the right site and at appropriate levels. None the less, until the perfect vector is developed, the choice of gene will remain crucially important in order to

compensate for the deficiencies of the vectors we currently have available (page 2, 1st paragraph, left column). Whatever its mechanism, no single genes can be a serious contender unless it has a demonstrable bystander effect (page 2, right column). The requirement for such a bystander effect stems directly from the poor delivery efficiency provided by current vectors (page 2, right column).

A genuine ability to target delivery systems to tumor cells distributed widely throughout the body of a patient would simultaneously increase real titers and efficacy. In truth, no such systemically targeted vectors exist yet. Injection of vectors into the bloodstream for the treatment of cancer requires not only that the vectors be targeted (to infect only tumor cells) but also that they by protected (from degradation, sequestration or immune attack) for long periods of time so that they can reach the appropriate sites for infection. Moreover, having reached such sites, the vectors must be able to penetrate into the tumor from the bloodstream before carrying out their targeted infection (page 4, bottom left column and top right column).

In addition, Rochlitz C. F. (Swiss Medicine Weekly, 131:4-9, 2001) teaches:

"that none of the more than one hundred clinical studies performed so far had formally proven efficacy of the approach [gene therapy] in any human disease. Although anecdotal reports of tumor responses are becoming more frequent in several human malignancies, the situation has not changed dramatically." (See page 8, bottom of page). Rochlitz continue "Main problems are still the lack of vectors with high transduction efficiency in vivo, the low tumor specificity of available systems, and our incomplete knowledge of molecular tumor pathology." (see pages 8-9).

Haupt (Exp. Biol. Med. 227:227-237 (2002)) teaches that:

"Accumulating evidence suggests the usefulness of DNA vaccination for treating various tumors in animal models, but results from clinical trials are lacking and the therapeutic benefit in the prevention or treatment of malignancies in human beings remains to be proven." (p. 233, Col. 2, ¶1),

and

"DNA vaccination is a promising strategy capable of inducing immune-mediated tumor reductions in animal model, but further studies are required to investigate the potential of DNA vaccination in antitumor treatment in human beings." (p. 234, Col. 1, ¶1).

Thus, at the time the application was filed, the state of the art for gene therapy was considered highly unpredictable.

Furthermore, it would take one skilled in the art an undue amount of experimentation to determine what route of administration (*e.g.* intravenous, dermal, nasal, rectal, vaginal, inhalation, or topical administration) would result in a therapeutic response using the polynucleotide comprising the sequence SEQ ID NO:8 much less any fragment of the polynucleotide. The state of the art for the route of administration for gene therapy as exemplified by Verma, *Nature*, Vol. 389, pages 239-242, 1997, indicates that factors including the nature of the diseases and/or disorders, the nature of a DNA and/or target tissue, and a delivery system and/or amounts of the DNA complexes employed in the delivery system that would generate a therapeutic effect *in vivo* must be considered for any gene therapy method to be successful (page 238, columns 1 and 2).

Therefore, the skilled artisan at the time the invention was made recognized the lack of predictability of the nature of the art and state of the prior art to which the instant invention pertains. Also, such disclosures clearly indicate that the amount of direction or guidance presented in the specification is limited, and would not permit a person skilled in the art to use the invention without undue experimentation at the time the invention was made.

In view of the lack of predictability of the art to which the invention pertains, the lack of established clinical protocols for effective proliferative disorders, namely, cancer therapies, undue experimentation would be required to practice using the claimed pharmaceutical composition the with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively treat any proliferative disorder and absent working examples providing evidence which is reasonably predictive that the claimed pharmaceutical composition is effective for treating any proliferative disorder, commensurate in scope with the claimed invention."

Applicants' allegations on p. 8 in ¶4 of the Response have been considered but are not found persuasive. Applicants allege "the previous patent application comprises experimental data showing the anti-cancer activity of the protein. Based on these data Applicants expect the protein to be useful as active ingredient as well as its polynucleotide to be useful in gene therapy."

Response to Arguments

Arguments of counsel alone are not found to be sufficient in overcoming the enablement rejection (MPEP 2144.03). Applicants have not addressed the art-based rejection that gene therapy was an unpredictable field of art at the time of filing and remains so today. Applicants have not supplemented the record with evidence showing that any polynucleotide of SEQ ID NO:8 or any one of its fragments could be targeted in vivo to any tissue associated with any proliferative disorder and induced to be expressed in vivo to produce a sufficient amount of a therapeutic protein. Gene therapy is an unpredictable art as established on the record. The ordinary artisan would not have been enabled as of the filing date to practice using the pharmaceutical composition comprising any polynucleotide without undue trial and error experimentation in order to even establish that the gene therapy composition could achieve a therapeutic endpoint.

The rejection is maintained.

New Grounds for Objection

Claim Objections

16. Claim 10 is objected to because of the following informalities: the claims recites an apparent typographical error for the phrase "one of the fragments of *the said* SEQ ID NO:13". Appropriate correction is required.

Conclusion

17. Claims 2 and 3 are objected to as depending from a rejected base claim.

18. Claims 4, 5, 8 and 9 are in condition for allowance.

19. The search of the polynucleotide sequences for SEQ ID NOS: 4, 5, 8, 9 and 11-13 did not identify any other sequences have 100% identity to the polynucleotide sequences encoding the heterocarpin protein (SEQ ID NOS 8, 9 and 13) and the cloning primers (SEQ ID NOS: 4, 5, 11 and 12).

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

/David J Blanchard/
Primary Examiner, Art Unit 1643